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G 510(k) SUMMARY

For the Bioretec ActivaScrew™ Interference

MANUFACTURER

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FINLAND

Contact person:
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Date prepared: March 13th, 2013

DEVICE NAME

Trade Name: Bioretec ActivaScrew™ Interference

Common Name: Biodegradable interference screw

AUG 2 8 2013

DEVICE CLASSIFICATION AND PRODUCT CODE

Product Code: MAI

Regulation Number: 21 CFR 888.3030

Device Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Classification Panel: Orthopedic

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PREDICATE DEVICES

1. Inion Hexalon™ Biodegradable ACL/PCL Screw (K071464)
2. Arthrex Bio-Tenodesis™ Screw from Tenodesis™ Screw Family (K010525, K011007, K020043, K041356, K051726)
3. Bioretec ActivaScrew™ (K062980, K072848, K081392)

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The **ActivaScrew™ Interference** is indicated for fixation of tissue, including ligament or tendon to bone, or a bone-tendon to bone in the presence of appropriate immobilization / controlled mobilization. Interference fixation is intended for surgeries of knee, shoulder, elbow, ankle, foot and hand/wrist.

The product family consists of fully threaded **ActivaScrew™ Interference**, diameters 4 – 10 mm and lengths 10 – 33 mm.

The **ActivaScrew™ Interference** is constructed of bioabsorbable poly(L-lactide-co-glycolide) (PLGA).

SUBSTANTIAL EQUIVALENCE TO MARKETED PRODUCTS

The ActivaScrew™ Interference bioabsorbable screw is substantially equivalent to biodegradable screws, intended for similar indications, which have been cleared through a 510(k) pre-market notification pathway.

The Bioretec ActivaScrew™ Interference has the same intended use and principles of operation, and very similar design characteristic as the predicate devices Inion Hexalon™ Biodegradable ACL/PCL Screw (K071464) and Arthrex Bio-Tenodesis™ Screw from Tenodesis™ Screw Family (K010525, K011007, K020043, K041356, K051726). The material of the ActivaScrew™ Interference is the same as the material of the previously cleared ActivaScrew™ (K062980, K072848, K081392).

The performance of the ActivaScrew™ Interference was compared to the predicate devices by pull-out testing, shear strength testing, inherent viscosity and dimensional stability testing.

These test results also verify that the performance of ActivaScrew™ Interference is sufficient for its indications, and that the device is substantially similar to its predicates with regard to its mechanical properties, and long term degradation properties. This performance testing does not raise any new questions of safety or effectiveness of the ActivaScrew™ Interference and demonstrates that the ActivaScrew™ Interference performs mechanically in a manner

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substantially similar to the tested predicate device. Thus, non-clinical tests and *in vitro* - testing determined that the ActivaScrew™ Interference has substantially similar performance as compared to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biorectec Limited
Ms. Mari Ruotsalainen
Quality and Regulatory Affairs Manager
Hermiankatu 22, Modulight Building
FI-33720 Tampere
Finland

August 28, 2013

Re: K130716
Trade/Device Name: Bioretec ActivaScrew™ Interference
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: July 5, 2013
Received: July 5, 2013

Dear Ms. Ruotsalainen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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F Indications for Use Statement

Submitter: Bioretec Ltd.
510(k) Number: K130716
Device Name: ActivaScrew™ Interference

Indications for Use:

The **ActivaScrew™ Interference** is indicated for fixation of tissue, including ligament or tendon to bone, or a bone-tendon to bone in the presence of appropriate immobilization / controlled mobilization. Interference fixation is intended for surgeries of knee, shoulder, elbow, ankle, foot and hand/wrist.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices